REMARKS

Claims 12-24 are currently pending in the application. Claims 17-18 are withdrawn. Claims 12, 16 and 19 are amended. Claims 20-24 are new.

The amendments and new claims find support in the specification and drawings as originally filed. For instance, the amendments to claim 12 are supported by the claims of issued parent patent 6,629,987, and also by the specification at page 2, line 12 to page 3, line 3, page 5, line 24 to page 6, line 13, and the specification thereafter. For instance, compression of the resilient members is described at page 6, lines 23-25, and is shown in FIG. 1.

Support for the amendments to claims 16 and 19, and for new claims 21 and 24, is found at page 6, line 25 to page 7, line 2 of the specification, which discloses that sensing bands (*e.g.*, for sensing electrical or thermal data of the tissue) can be placed on the resilient members for "sensing properties of the tissue near the treatment area to which the catheter is delivered". The sensing of such data can therefore form a part of the catheter-based procedure of claims 12 and 20.

New claim 20 finds support at page 8, line 13 to page 14, line 11, and Figs. 3 – 8. These portions of the specification disclose that the device can have resilient members with free distal ends which can be advanced radially outward to engage the surrounding tissue. See, *e.g.*, page 3, lines 4-9, page 8, lines 13-21, and page 9, lines 8-17 *et seq.* The control mechanisms are discussed at page 9, lines 23-28, and page 10, lines 9-12.

No new matter is added.

ELECTION/RESTRICTION

The action characterized amended claim 16 and new claim 19 as directed to an invention distinct from that originally claimed, on the grounds that the original claims "were to a method

of relieving symptoms of ischemia," and that amended 16 and 19 are "directed to a method of detecting data."

Claims 16 and 19 both depend from claim 12, which is directed to a method of performing a catheter-based procedure to a particular treatment site. Claims 16 and 19 have been amended to recite that the procedure can include the collection of thermal or electrical data. This is supported by the specification at page 6, line 25 to page 7, line 2, which states that "[s]ensing bands 46 may be placed at the midpoints 40 of vanes 16 for the purpose of contacting and sensing properties of the tissue near the treatment area to which the catheter is delivered. Sensing bands 46 may be configured to perform a variety of useful functions such as mapping of the tissue, detecting electrical or thermal data of the tissue, or for other purposes."

Applicants request that claims 16 and 19 be rejoined with the claims currently under examination.

THE INVENTION

Applicants' invention is a method of stabilizing the distal end of a catheter while performing a catheter-based procedure. In certain medical procedures, placement of the distal end of the catheter may be critical, and it is sometimes difficult to prevent movement of its distal end during the procedure. Applicants' method uses a catheter with proximal and distal ends and a tubular shaft, and a radially extendible tissue engagement mechanism at the distal end. The catheter is navigated so that its distal end is adjacent the intended treatment site, causing the engagement mechanism to extend into engagement with the tissue, and performing the procedure while the engagement mechanism is in its extended position.

The radially extendible tissue engagement mechanism can comprise, for example, flexible vanes mounted parallel to the catheter and attached at proximal and distal joints 24, 22 (see, *e.g.*, Fig. 1). When compressive force is applied, the vanes expand radially (see Fig. 1) and contact the surrounding tissue.

The radially extendible tissue engagement mechanism also can comprise, for example, a plurality of resilient members joined to the tubular shaft, and at least one control mechanism that is configured to be manipulated by a user to actuate the resilient members from a retracted position to an extended position. Each of the resilient members has proximal and distal ends, where the proximal ends are associated with the control mechanism, and the distal ends are free, so that by moving of the control mechanism in the distal direction, the distal ends of the members to advance radially outward away from the shaft to an extended position (see, *e.g.*, Figs. 3-7).

Once the tissue engagement mechanism is activated, the vanes or resilient members are extended into engagement with the surrounding tissue, thereby preventing movement of the distal end of the catheter.

THE CITED ART

Segal *et al.* (U.S. Patent App. Pub. No. 2003/0100886; "Segal")

U.S. Patent App. Pub. No. 2003/0100886 to Segal *et al.* discloses a device for mechanically dilating and enlarging a vessel, and delivering a medicament. The device includes a cylindrically shaped expansion member 31 with an inner flow passage 34 with a variable diameter. The expansion member is comprised of a plurality of flexible elongate filaments 36 which extend helically about the central axis (paragraph [0052]), and are secured at their proximal and distal ends to a proximal and distal collar 41, 42 (paragraph [0053]). When the proximal and distal ends of the expansion member are moved toward each other, the filaments are forced to expand radially outward (paragraph [0055]). The movement of the filaments outward causes the inner flow passage 34 to increase in diameter (end of paragraph [0052]; paragraph [0055]).

Makower *et al.* (U.S. Pat. No. 6,602,241; "Makower")

U.S. Pat. No. 6,602,241 to Makower *et al.* discloses a device for delivery of substances to target sites located outside of blood vessels in the body of a patient. A catheter capable of penetrating the vessel wall 11 is inserted into the vasculature, and positioned near the target extravascular site. A penetrator 27 is advanced out of the catheter, through the vessel wall and into the target area. A delivery catheter is then passed through the lumen of the penetrator, and the substance is delivered to the target area. The delivery catheter also can include a balloon (see, *e.g.*, Fig. 7) or occlusion member, which can be advanced into a vein in order to block it, so as to prevent the delivered substance from being carried away by normal venous blood flow (Abstract).

THE REJECTIONS

Claim Rejections Under 35 U.S.C. § 102

Reconsideration is requested of the rejection of claims 12-13 and 15 as anticipated by Segal.

Amended claim 12 discloses that the resilient members lie parallel to the longitudinal axis of the tissue engagement mechanism in the absence of a compressive load. The device disclosed in Segal possesses filaments which are wound helically around the central longitudinal axis. The filaments do not lie flat, in either the presence or absence of a compressive load.

Where Segal does not disclose that the filaments lie parallel to the longitudinal axis, it cannot be considered as anticipating any of claims 12-16, all of which include limitations, in varying degrees of specificity, to resilient members that lie parallel to the longitudinal axis of the tissue engagement mechanism in the absence of a compressive load.

Applicants request that the rejection on this basis be reconsidered and withdrawn.

Reconsideration is also requested of the rejection of claims 12-15 as anticipated by Makower.

Like the Segal reference, Makower does not disclose a device with radially expandable resilient members that lie parallel to the longitudinal axis of the tissue engagement mechanism in the absence of a compressive load. Instead, Fig. 7 of Makower discloses a balloon which allows the substance to diffuse into the tissue while preventing cellular material from entering the device.

Where Makower does not disclose a plurality of resilient members that lie parallel to the longitudinal axis, it cannot be considered as anticipating any of claims 12-15, all of which include limitations, in varying degrees of specificity, to resilient members that lie parallel to the longitudinal axis of the tissue engagement mechanism in the absence of a compressive load.

Applicants request that the rejection on this basis be reconsidered and withdrawn.

New claims 20-24 disclose that the radially extendible tissue engagement mechanism includes resilient members with their proximal ends joined to the shaft and in association with the control mechanism, and with distal ends which are free, so that movement of the control mechanism causes the distal ends of the members to advance radially outward and away to an extended position. This is not disclosed in either the Segal or the Makower reference.

Applicant submits that all of the claims are now in condition for allowance, which action is requested. Please apply any charges or credits to Deposit Account No. 50-1721, Reference No.: 0506765.0066.

Respectfully submitted,

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